K083680

Summary Information

FEB 2 6 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4041 email: mhanna1@ocdus.jnj.com Contact Person: Marlene A. Hanna
2.	**Preparation date**	Date Special 510(k) prepared: December 10, 2008
3.	**Device name**	Trade or Proprietary Name: VITROS Chemistry Products K^+ DT Slides Common Name: potassium test Classification Name: Potassium test system (21 CFR 862.1600) VITROS Chemistry Products DT Calibrator Kit Common Name: calibrator Classification Name: Calibrator (21 CFR 862.1150)
4.	**Predicate device**	The VITROS Chemistry Products K^+ DT Slides (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to the VITROS Chemistry Products K^+ DT Slides (current slide) and VITROS Chemistry Products DT Calibrator Kit.

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510(k) Summary, Continued

5. Device Description

The VITROS Chemistry Products K^+ DT Slide assay is performed using the VITROS Chemistry Products K^+ DT Slide and the VITROS Chemistry Products DT Calibrator Kit on the VITROS DT60/DT60 II Chemistry Systems. The VITROS K^+ DT Slide is a multilayered, analytical element coated on a polyester support that uses direct potentiometry[1] for measurement of potassium ions. All reactions necessary for a single quantitative measurement of potassium take place within the multi-layered analytical element of a VITROS Chemistry Products K^+ DT Slide. The slide consists of two ion-selective electrodes, each containing valinomycin (an ionophore for potassium), a reference layer, and a silver layer and a silver chloride layer coated on a polyester support.

VITROS Chemistry Products K^+ DT Slides use ion-selective electrodes for potentiometric measurements of ionic potassium. Ionic potassium determinations are made by simultaneously depositing 10 uL each of a reference fluid and a sample fluid on separate halves of the VITROS Chemistry Products K^+ DT Slide. The electrode receiving the reference fluid is identified as the reference electrode. A paper bridge connects the reference electrode and the indicator electrode, which receives the sample fluid. A stable liquid junction between the two fluids is formed in the paper bridge. The potassium ions in the tested reference and sample fluids migrate to the silver/ silver chloride layers and establish equilibrium.

After an incubation period, the electrometer in the VITROS Chemistry System measures the potential difference between the reference and indicator electrodes. Each electrode responds to the activity of potassium ions in the respective fluids to produce a potential for the concentration cell. The VITROS DT60/DT60II Chemistry System's microprocessor uses this measurement and the stored calibration parameters to determine the concentration value of the potassium ion in the sample fluid. The test result is reported in millimoles per liter (mmol/ L).

VITROS Chemistry Products DT Calibrator Kit contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from bovine serum albumin and processed bovine serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added. The companion diluents are prepared from processed water to which inorganic salts have been added.

The VITROS DT60/ DT60 II Chemistry System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

6.	**Device intended use**	VITROS Chemistry Products K^+ DT Slides For *in vitro* diagnostic use only. VITROS K^+ DT Slides quantitatively measure potassium (K^+) concentration in serum and plasma. VITROS Chemistry Products DT Calibrator Kit For *in vitro* diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for the quantitative measurement of ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl-, Co2, CREA, CRSC, Fe, GGT, GLU, HDLC, K+, LAC, LDH, LIPA, Mg, Na+, NH3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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7. **Comparison to predicate device**

The VITROS Chemistry Products K^+ DT Slide (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to VITROS Chemistry Products K^+ DT Slide and VITROS Chemistry Products DT Calibrator Kit, which were Cleared by the FDA for *in vitro* diagnostic use.

VITROS Chemistry Products K^+DT Slide: (K912844, cleared September 4, 1991)
VITROS Chemistry Products DT Calibrator Kit:(K082099, cleared August 21, 2008).

Table 1 lists the characteristics of the tests performed using the VITROS K^+ Slide (modified) and the VITROS K^+ Slide (current).

Table 1. List of VITROS Chemistry Products K^+ DT Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS Chemistry Products K^+ DT Slide (Modified)	Predicate Device VITROS Chemistry Products K^+ DT Slide (Current)
Intended Use	No Change.	For *in vitro* diagnostic use only. VITROS K^+DT Slides quantitatively measure potassium (K^+) concentration in serum and plasma.
Fundamental scientific technology	No Change.	Dry, multilayered slide utilizing direct potentiometry
Reactive Ingredients per cm^2	No Change.	Silver 0.4 mg; silver chloride 0.2 mg; sodium chloride 0.2 mg; potassium chloride 63 µg; and valinomycin 55 µg.
Sample type	No Change.	Serum, plasma
Instrumentation	No Change.	VITROS DT Systems
Manufacturing Process of the ISE baseweb* (Ag/AgCl and Support Layers of the Cl^- DT Slide)	Magnetic sputter deposition	Electron beam evaporation
Composition of ISE baseweb component	Ag/AgCl concentration: No change Nickel Stripes: NiCr (80% Nickel, 20% Chromium)	Ag/AgCl concentration: Silver 0.4 mg and silver chloride 0.2 mg Nickel Stripes: Ni (99+% Nickel)

*ISE (Ion-Selective Electrode) baseweb= Polyethylene terephthalate film (substrate used for metallized film) coated with silver (Ag)/ silver chloride (Ag/Cl) and striped with nominal nickel (Ni) stripes. The "ISE baseweb" refers to the Ag/ AgCl with nickel stripes layer and support layer of the VITROS Chemistry Products K^+ DT Slide.

No modifications were made to VITROS Chemistry Products DT Calibrator Kit.

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8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the VITROS Chemistry Products K^+ DT Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured potassium values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products K^+ DT Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics Inc.
c/o Marlene Hanna
Regulatory Affairs Manager
100 Indigo Creek Drive MC00882
Rochester, NY 14626-5101

FEB 2 6 2009

Re: k083680
Trade/Device Name: VITROS Chemistry Products K+ DT Slides
VITROS Chemistry Products DT Calibrator Kit
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Code: CEM, JIX
Dated: January 26, 2009
Received: January 27, 2009

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083680

Device Name: VITROS Chemistry Products K^+ DT Slides
VITROS Chemistry Products DT Calibrator Kit

Indications for Use: VITROS Chemistry Products K^+ DT Slides quantitatively measure potassium (K^+) concentration in serum and plasma using VITROS DT60 and DT60 II Chemistry Systems. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases or conditions characterized by low or high blood potassium levels. For *in vitro* diagnostic use only.

VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for the quantitative measurement of ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl-, Co2, CREA, CRSC, Fe, GGT, GLU, HDLC, K+, LAC, LDH, LIPA, Mg, Na+, NH3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems. For *in vitro* diagnostic use only.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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